

Art Unit: 1648

### DETAILED ACTION

The amendment and response submitted on Oct. 14, 2009 have been noted. Claims 1, 14-15, 22, 26, 30, 34, 38, 42, 46, 50, 54 have been amended. Claims 11-13 have been canceled. Claims 1-10, 14-57 are pending and considered.

Applicants' amendment of the claimed human cell line to K562 has overcome the objection of the priority of the pending and the rejection under *35 USC § 112* 1<sup>st</sup> paragraph.

#### *Rejoinder Practice*

1. The elected independent claim 1 and its depended claims with the elected species of GM-CSF and LAM-2 antigen are allowable. The species restrictions requirement for immunomodulators and EBV antigens cited in claims 2-4 and claims 5-9 set forth in the Office action mailed on March 25, 2008, have been reconsidered in view of the allowability of the claim 1 and its depended claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirements among different species as set forth in the Office action mailed on March 28, 2008 are hereby withdrawn.** Claims 2-4 read on different species and 5-9 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

2. In view of the withdrawal of the restriction requirement, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

#### EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

4. Authorization for this examiner's amendment was given in a telephone interview with Devadas K. Sendi on Jan 15, 2010.

5. The application has been amended as follows:

Art Unit: 1648

Claim 1 (currently amended). In line 1 after "cell line" please insert --- K562 --- In line 3 after "immunomodulator" insert --- selected from the group consisting of macrophage colony factor (M-CSF), granulocyte colony stimulating factor (G-CSF), granulocyte-macrophage colony stimulating factor (GM-CSF)--- In line 4 after "(EBV)" please delete ", wherein the cell line is K562"

Claim 14 (currently amended) In line 1 after "comprising" please delete "a human cell line, " and insert --- the isolated human cell line K562 of claim 1 and a pharmaceutical accepted carrier or diluent --- In line 1 please delete rest of citation of the claim.

Claim 14 (reiterated) A composition comprising the isolated human cell line K562 of claim 1 and a pharmaceutical accepted carrier or diluent.

Claim 16 (currently amended) In line 5, please delete ", wherein the cell line is K562"

Claim 26 (currently amended) In line 5, please delete ", wherein the cell line is K562"

Claim 42 (currently amended). In line 4 after "stimulated" please delete "wherein the cell line is K562"

Claim 50 (currently amended). In line 2 after "EBV-associated cancer" please delete "which method" In line 3 after "human cell line" please insert --- K562, --- In line 9 after "stimulated" please delete ", wherein the cell line is K562"

Please cancel claims 3-9, 15, 22-23, 30-41 and 46-57.

**Claims 1, 2, 10, 14, 16-21, 26-29 and 42-45 are allowed.**

1. **The following is an examiner's statement of reasons for allowance:**
2. While EBV or EBV origin of replication (oriP) had been used transfecting a cell line including human K562 prior to the current Application was filed, state of art teaches away from the claimed subject matter as evidenced by US patent No. 6,464,973B1 to Levitsky et al. They et al. teach that if K562 cell line is used as a universal bystander cell line to express GM-CSF, the cell line should be absence of an EBV genome, its associated nuclear antigen as well as a receptor for EBV (Column 4). Therefore, no prior art teaches or suggests co-expressing an EBV

Art Unit: 1648

antigen with a GM-CSF family cytokine together in K562 cell line and using said transfected cell line to treat an EBV-associated cancer.

3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mondesi Robert can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/

Examiner, Art Unit 1648

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645